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Invention: SURGICAL INSTRUMENT

Applicant: James M. Rhodes, et al.

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Examiner: Kristin D. Rogers

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2006**

APPEAL BRIEF

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/Stephen J. Manich/
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December 13, 2006
Date of Signature

This Appeal Brief is submitted electronically in support of the appeal from the Examiner's August 10, 2006 final rejection of claims 1-7, 9, 11-19 and 21-24, and is submitted within two months of the November 9, 2006 filing date of the Notice of Appeal. Please charge Deposit Account No. 10-0750 with reference to our matter DEP5054 in the amount of \$500.00 for the fee to file this Appeal Brief. It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be credited, to Account No. 10-0750 with reference to file DEP5054.

REAL PARTY IN INTEREST

The real party in interest is DePuy Products, Inc., the assignee, pursuant to an assignment recorded in the records of the U. S. Patent and Trademark Office at reel 014263, beginning at frame 0132.¹

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants that will directly affect or be directly affected by, or have a bearing on the Board's decision in the present appeal.

STATUS OF CLAIMS

Claims 1-7, 9, 11-19 and 21-24 were finally rejected in the Office Action dated August 10, 2006.

Claims 8, 10, 20 and 25-45 are withdrawn from consideration as being drawn to a non-elected species.

Each of claims 1-7, 9, 11-19 and 21-24 is appealed.

A copy of pending claims 1-7, 9, 11-19 and 21-24 is attached hereto in an Appendix.

STATUS OF AMENDMENTS

Appellant has filed no amendments subsequent to the August 10, 2006 final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1:

Claim 1 is directed to a surgical instrument, and encompasses the three embodiments of surgical instruments shown at 10 in FIGS. 1-6, at 12 in FIG. 8 and at 110 in FIGS. 16 and 18. The instrument has a proximal end (16 in FIGS. 1-6 and 8, 120 in FIG. 16) and a distal end (18 in FIGS. 1-6 and 8, 18 in FIG. 18). The instrument includes a handle 20, a hollow elongate support member 26, a slide member 82, a lever 30, 30A, a surgical implement 28, 28A (which may comprise distance

¹ The Recordation Notice received from the United States Patent and Trademark Office misspells the assignee as "DUPUY". A request for correction has been sent via facsimile to the Assignment Division.

references 78, 80, 166, 168, see page 14, lines 12-19) and a spring 104. (see page 11, lines 6-9, page 14, lines 17-19, page 19, lines 5-6, FIGS. 5-6, 8 and 16-18) The hollow elongate support member 26 encompasses the support member shown in FIGS. 20-24 and is described at page 12, lines 10-22. The slide member 82 has a through-slot 92 between the two ends (see page 18, lines 8-10, FIGS. 5-6, 8, 13 and 17-18). A cam 90, 90A on the lever 30, 30A is received in the slot 92 in the slide member 82 (see page 18, lines 8-10, FIGS. 5-6, 8 and 18). The distal end of the slide member 82 is connected to the surgical implement 26, 26A (see page 18, lines 10-19). The slide member 82 and the surgical implement 26, 26A are capable of being moved reciprocally in a linear proximal-distal direction by pivoting the lever 30, 30A (see page 18, line 20- page 19, line 2, FIGS. 1-6). There is no mechanical connection between the lever 30, 30A and the slide member 82 (see page 18, lines 9-10).

Independent Claim 5:

Claim 5 is directed to a modular surgical instrument comprising an actuator module 110 and a discrete tool module 112. The actuator module 110 comprises a handle 114 and an integral support portion 118. (see page 20, lines 17-21, FIGS. 16-18) The support portion 118 has proximal and distal ends 120, 122, a support surface 124 between the proximal and distal ends, and is substantially open above the support surface 124. (see page 20, lines 17-21, FIG. 16) A lever 30A is pivotally connected to the support portion 118 of the handle 114, and has a drive portion 88A that extends through an opening 126 in the support surface 124 of the handle 114. (see page 21, lines 1-9, FIGS. 16 and 18) The tool module 112 is an assembly of a hollow housing 144, a discrete hollow elongate support member 26, a discrete surgical instrument 28 (which may comprise distance references 78, 80, 166, 168, see page 14, lines 12-19) and a discrete slide member 82. (see page 22, line 5 – page 23, line 5) The hollow elongate support member 26 encompasses the support member shown in FIGS. 20-24 and is described at page 12, lines 10-22. The slide member 82 has a drive surface within the housing of the tool module. (see page 22, lines 7-9 and page 18, line 20 – page 19, line 1, FIGS. 17-18) The surgical implement 28 can reciprocate in the elongate support member 26 (see page 23, lines 6-8) and has a proximal portion that extends into the housing of the tool module (see page 23, lines 3-5, FIGS. 17-18). The actuator module 110 and tool module 112 are capable of being assembled and disassembled so that at least one of the modules 110, 112 can be reused

independent of the other module. (see page 23, lines 11-14) When the actuator module 110 and tool module 112 are assembled, the drive portion 88A of the lever 30A engages the drive surface 100 of the slide member 82 so that the slide member 82 and surgical implement 28 can be moved in the distal direction by squeezing the trigger portion 86A of the lever 30A. (see page 29, lines 13 – 21 and page 30, line 12-16).

Independent Claim 16:

Claim 16 is directed to a disposable surgical tool module 112 for use with a separate actuator module 110 (see page 22, line 5 through page 23, line 5). The surgical tool module 112 comprises a housing 144, a discrete hollow elongate support member 26, a surgical implement 28 (which may comprise distance references 78, 80, 166, 168, page 14, lines 12-19) and a slide member 82. (see page 22, line 5 – page 23, line 5) The hollow elongate support member 26 encompasses the support member shown in FIGS. 20-24 and is described at page 12, lines 10-22. The slide member 82 and the surgical implement 28 are capable of reciprocal motion in the proximal-distal direction (see page 23, lines 6-10). The housing 144 has an opening 111 aligned with the slot 92 of the slide member 82. (see page 22, lines 16-18, FIGS. 17-18). The tool module 112 is free from any structure for moving the slide member 82 in the distal direction. (see FIG. 17).

Independent Claim 22:

Claim 22 is directed toward a surgical instrument comprising a handle 20, a hollow elongate support member 26, a surgical implement 28 (which may comprise distance references 78, 80, 166, 168, page 14, lines 12-19), a lever 30, 30A and a slide member 82. (see page 11, lines 6-9, page 14, lines 17-19, page 19, lines 5-6, FIGS. 5-6, 8 and 16-18) The hollow elongate support member 26 encompasses the support member shown in FIGS. 20-24 and is described at page 12, lines 10-22. The surgical implement 28 extends through the elongate support member 26 and is capable of reciprocating in the proximal-distal direction in the elongate support member 26. (see page 18, lines 3-18) The lever 30, 30A extends through an opening 34, 111 in the handle 20. (see page 11, lines 15-16, page 22, lines 16-18, FIGS. 5-6, 8 and 18) The slide member 82 has a drive surface 100 engaging the drive portion 88, 88A of the lever 30, 30A, and is capable of reciprocal motion in the proximal-distal direction. (page 18, line 20 – page 19, line 1) A pair of elongate substantially

flexible distance references 166, 168 are connected at one end to the slide member 82 and extend out of the distal end of the elongate support member 26. (see page 25, lines 3-18, FIGS. 23, 24) The elongate support member 26 has a substantially cylindrical portion 152 and a pair of discrete elongate tubes 154, 156 extending from the substantially cylindrical portion 152. (see page 23, line 19 - page 24, line 6, FIGS. 20-22) One of the elongate substantially flexible distance references 166 extends through one of the discrete elongate tubes 154 and the other elongate substantially flexible distance reference 168 extends through the other of the discrete elongate tubes 156. (see page 23, lines 3-18) Each elongate tube 154, 156 and each distance reference 164, 166 has a beveled distal end 162, 164, 170, 172. (see page 24, line 19 – page 26, line 2, FIGS. 20 and 22-24)

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

This appeal presents five grounds of rejection:

- I. Whether claims 1-4 are unpatentable under 35 U.S.C. §112, first paragraph as being based on a non-enabling disclosure.
- II. Whether claims 16-19 are anticipated under 35 U.S.C. §102(b) by Shutt et al., U.S. Patent No. 5,507,772.
- III. Whether claims 1-4 are unpatentable under 35 U.S.C. §103 over Lucey et al., U.S. Patent No. 5,782,834, in view of Shutt et al., U.S. Patent No. 5,507,772.
- IV. Whether claims 5-6 and 11 are unpatentable under 35 U.S.C. §103 over Steadman et al., U.S. Patent No. 5,928,252, in view of Troutner et al., U.S. Patent No. 4,091,880.
- V. Whether claims 22-24 are unpatentable under 35 U.S.C. §103 over Shutt et al., U.S. Patent No. 5,507,772, in view of Matthews et al., U.S. Patent No. 6,427,351.

ARGUMENT

- I. THE BOARD IS URGED TO REVERSE THE REJECTION OF CLAIMS 1-4 UNDER 35 U.S.C. §112, FIRST PARAGRAPH: CLAIMS 1-4 ARE BASED ON AN ENABLING DISCLOSURE.

The Examiner's rejection is based upon the statement that "it is unclear as to how the claimed invention can function without a mechanical connection between the lever and the slide member." However, the specification teaches:

- “To effect reciprocal motion, the cam portion 90 of the lever 30 is received in a slot 92 of the slide member 82. There is no mechanical connection between the lever 30 and the slide member 82 in the first instrument 10.” (page 18, lines 8-10).
- “As shown in FIGS. 5-6 and 13, the slide member 82 has a drive surface 100 at the distal end of the slot 92 that is engaged by the cam 90 of the drive portion 88 of the lever 30 to cause the slide member 82 and distance references 78, 80 to reciprocate.” (page 18, line 20- page 19, line 1).
- “Assembly of the lever 30, 30A with the slide member 82 is simple in each of the embodiments 10, 12, 14. For the first two embodiments, 10, 12, when the slide member 82 is in position in the handle or the housing, the slot 92 in the slide member 82 is visible from the underside of the handle by looking through the lever slot 34. The lever 30, 30A can be assembled with the slide member 82 by inserting the drive portion 88, 88A of the lever 30, 30A through the entry slot 34 until the cam portion 90, 90A of the lever 30, 30A is received within the slot 92 of the slide member 82.” (page 29, lines 3-9).
- “For the modular embodiment 14 of FIGS. 16-18, prior to assembly, the slot 92 in the slide member 82 is visible through the entry 111 slot in the bottom of the housing 144 so the drive portion 88A of the lever 30A can be easily guided through this housing entry slot 111 and into the slide member slot 92 as the tool module 112 and actuator module 110 are pushed together. With the cam portion 90A of the lever 30A of the actuator module 110 aligned to be received in the slide member slot 92, the two modules 110, 112 can be pushed together until the housing 144 is supported by the concave support structure 118 and movement is constrained by the retaining structures at the proximal and distal ends 120, 122 of the handle.” (page 29, lines 13-21).
- “The surgeon can squeeze the trigger portion 86, 86A of the lever proximally causing the cam portion 90, 90A of the lever 30, 30A to pivot distally against the drive surface 100 of the slot 92 of the slide member 82, thereby causing the distance references 78, 80, 166, 168 or rods or tangs 180, 182 to move distally.” (page 30, lines 12-16).

Moreover, examples of suitable dimensions and offsets for the levers 30, 30A are provided in the specification:

- “As shown in FIG. 14, the center of the cam portion 90 is laterally offset from the center of the hole 85 by a distance of about 2.5 mm in the first instrument, shown at d_4 in FIG. 14, and is longitudinally offset by a distance of about 1 inch or 2.5 cm, shown at d_5 in FIG. 14. The end of the trigger portion 86 is longitudinally offset from the center of the hole 85 by a distance of 6.8 cm, shown at d_6 in FIG. 14, and laterally offset from the center of the hole 85 by a distance of 7mm, shown at d_7 in FIG. 14. As shown in FIG. 15, the cam portion 90 of the lever 30 of the first instrument 10 has a thickness t_1 of less than 2 mm; the trigger portion 86 has a thickness t_2 of about 5-6 mm. It should be understood that all of the above dimensions are provided as examples only; the present invention is not limited to any particular dimension unless expressly set forth in the claims. Moreover, as described below with respect to the second instrument 12, these dimensions for the lever 30 can be varied; for example, the lateral offset of the cam portion 90 d_4 can be increased.” (see page 17, line 12 – page 18, line 2).
- “In FIG. 8, the lever designated 30A is shaped differently from the lever 30 of the first instrument 10; the distance d_4 is increased by 4 mm to 6.6 mm and the distance d_5 is increased by about $\frac{1}{2}$ inch or 12.5 mm to about 1.5 inches or 38 mm. In addition, the potential range of travel for the slide member 82 and the distal ends of the distance references 78, 80 (shown at d_3 in FIG. 19) is increased from 20 mm, for example, for the first instrument 10, to 45 mm, for example, for the second instrument 12.” (page 19, line 18 – page 20, line 1).

In addition, FIGS. 5-6, 8, 18 illustrate the cam or drive portion of the lever received within the slot of the slide member and engaging the drive surface of the slide member without being connected together.

Accordingly, the specification describes the relationship between the lever and the slide member sufficiently to support claims 1-4: as described and illustrated, part of the drive portion 88, 88A of the lever 30, 30A is received in the slot 92 in the slide member 82. The drawings illustrate the relationship between the slot 92 of the slide member 82 and the drive portion 88, 88A of the lever 30, 30A in both the retracted and extended positions. The specification teaches that the cam portion 90, 90A of the drive portion 88, 88A engages the drive surface 100 of the slide member 82

so that pivoting of the lever 30, 30A pushes the slide member 82 to effect the desired movement. The specification teaches how to assemble the components. Together with the drawings, the specification enables one of ordinary skill in the art to make and use the invention of claims 1-4. For this reason, the Board is urged to reverse the rejection of claims 1-4 under 35 U.S.C. §112.

Conclusion regarding claims 1-4 and 35 U.S.C. §112, first paragraph

Based on the above, the Examiner has not established a proper §112, first paragraph rejection with regard to Appellant's claim 1. As such, the rejection of independent claim 1, and claims 2-4 depending either directly or indirectly from claim 1, should be reversed.

II. REJECTION OF CLAIMS 16-19 UNDER 35 U.S.C. §102(B) OVER U.S. PATENT NO. 5,507,772 TO SHUTT ET AL.

Claims 16-19

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). As will be discussed in detail below, Appellant asserts that the §102(b) rejection of claims 16-19 based on Shutt et al. is improper.

The rejection of claims 16-19 is based upon an interpretation of Shutt et al. that characterizes element 142 of Shutt et al. as a "housing," member 154 as a "slide member" and element 156 as a "slot." Although the Examiner indicates that Shutt et al. has a hollow elongate support member at the distal end of the housing 142, the Examiner has not identified the element of Shutt et al. that corresponds with a hollow elongate support member and it is difficult to perceive what this element could comprise in Shutt et al while meeting the limitations in claim 16, which requires that the hollow elongate support member be discrete from the housing and that it have a proximal end *received within* the housing. If element 142 in Shutt et al. is a housing, the only elements *received within* element 142 are elements 152 and 154, which the Examiner has characterized as the surgical implement and slide member. Element 152 cannot comprise both the surgical implement and the elongate support member because claim 16 requires that at least part of the surgical implement extend through the hollow elongate support member; element 152 cannot extend through itself.

Element 154 cannot comprise both the slide member and the hollow elongate support because claim 16 requires that the slide member be connected to the proximal end of the surgical implement between the proximal end of the housing and the proximal end of the hollow elongate support member. In sum, the Examiner's rejection does not identify how all of the elements and limitations of claim 16 could be present in Shutt et al. Accordingly, claim 16 and its dependent claims 17-19 are patentable over Shutt et al. and the Board is urged to reverse the rejection of claims 16-19 under 35 U.S.C. §102(b).

Conclusion regarding claims 16-19 and 35 U.S.C. §102(b)

Based on the above, the Examiner has not established a proper §102(b) rejection with regard to Appellants' claim 16. As such, the rejection of independent claim 16, and claims 17-19 depending either directly or indirectly from claim 16, should be reversed.

III. REJECTION UNDER 35 U.S.C. §103(a) OVER LUCEY ET AL. (U.S. PAT. NO. 5,782,834) IN VIEW OF SHUTT ET AL. (U.S. PAT. NO. 5,507,772).

Claims 1-4

The Examiner's rejection recognizes that Lucey et al. "lacks an integral cam received in the through-slot of the slide member, a drive surface, and a through-slot at the drive surface." The Examiner points to Shutt et al., and more particularly to "through-slot 156 of slide member 154, and through-slot 218 at drive surface 142 located on the proximal side of support member 20 for the purpose of receiving integral cam 210 (FIG. 16)."

The Examiner's characterization of the structures of Shutt et al. is incorrect. First, slot 156 of Shutt et al. is part of support member 142, not part of the drive actuator 154: "The drive assembly illustrated in FIG. 16 reduces bowing of actuator 154 out of the elongated slot 156 of support member 142 as drive actuator 154 moves back and forth in the direction of arrows 212 and 214." (col. 14, lines 33-36). Second, slot 218 is not part of the actuator 154, but is part of the support member 142, and receives a tab 216 on the actuator 154: "Drive actuator 154 includes a tab 216 which moves back and forth inside slot 218 formed in support member 142. Therefore, slot 218 limits the range of movement of drive actuator 154 relative to support member 142. (col. 14, lines

26-29). Instead of a through-slot, Shutt et al. rely on notches for the drive connection: “The drive actuator 154 includes a notched portion defined by walls 208 and 209 which engages a drive portion 210 on movable handle 224. Preferably, drive portion 210 has a triangular shape to engage first surface 208 of drive actuator 154 to move drive actuator 154 in the direction of arrow 212 when movable handle portion 24 moves in the direction of arrow 213. Drive portion 210 engages second drive surface 209 to move drive actuator 154 in the direction of arrow 214 when movable handle portion 24 moves in the direction of arrow 215.”

Accordingly, neither Lucey et al. nor Shutt et al. disclose or suggest providing a slide member with a through-slot that receives at least part of an integral cam of a lever, and Shutt et al. does not provide any motivation to provide a through-slot to receive a cam member.

Conclusion regarding claims 1-4 and 35 U.S.C. §103(a)

Based on the above, the Examiner has not established a proper §103(a) rejection with regard to Appellants’ claim 1. As such, the rejection of independent claim 1, and claims 2-4 depending either directly or indirectly from claim 1, should be reversed.

IV. REJECTION UNDER 35 U.S.C. §103(a) OVER STEADMAN ET AL. (U.S. PAT. NO. 5,928,252) IN VIEW OF TROUTNER ET AL. (U.S. PAT. NO. 4,091,880)

Claims 5-6 and 11

A proper rejection under §103(a) has not been established in regard to independent claim 5. In the first place, the Examiner has characterized parts of element 21 of Steadman et al. as both the support surface of the actuator module and the housing of the tool module when Steadman et al. do not disclose, suggest or show the portions of element 21 being discrete components capable of being disassembled and when neither reference suggests how one would split the components of Steadman et al. to work as a separate module that can be used with a removable power pack as disclosed in Troutner et al.

Steadman et al. teaches that “the driver assembly is able to produce countering forces on the surgical device when desired. For example, the driver assembly is capable of providing a force

greater than that which is provided by the operator such that one gentle squeeze of the trigger arm translates into a forceful push of the needle. This enables the operator to penetrate hard tissue or cartilage with the needle with ease. Alternatively, the driver is able to produce a force less than that provided by the operator. In this case, one squeeze of the trigger arm produces a gentle push of the needle thereby enabling the operator to perform delicate puncturing of soft tissue with significantly reduced chance of error which minimizes patient trauma.” (col. 2, lines 44-56). To translate a gentle squeeze of the trigger into a greater force, Steadman et al. use a system of springs and lever arms (see col. 11, lines 1-8). Given that Steadman et al. teaches that the desired forces can be achieved with the mechanical structures shown, what would have motivated one of ordinary skill in the art to change the Steadman et al. devices to use a removable power pack instead? Without adding the power pack, what advantage would there be to modifying Steadman et al. by incorporating select features from Troutner et al. to produce a modular device?

Moreover, assuming one of ordinary skill in the art were motivated to combine Steadman et al. and Troutner et al., what would motivate that person to use a lever driven mechanism instead of the power drive mechanism of Troutner et al.? If one of ordinary skill in the art were motivated to combine the teachings of Troutner et al. with Steadman et al., wouldn't that person be likely to use the motor drive and miter gears 60, 72 of Troutner et al. to drive the needle 14 of Steadman et al., in which case there would be no reason to have a lever engaging a drive surface of a slide member. In such a case, combining Troutner et al. with Steadman et al. would lead that person away from the claimed invention.

Conclusion regarding claims 5-6 and 11 under 35 U.S.C. §103(a)

Based on the above, the Examiner has not established a proper §103(a) rejection with regard to Appellants' claim 5. As such, the rejection of independent claim 5, and claims 6 and 11 depending either directly or indirectly from claim 5, should be reversed.

Claims 7 and 9

Claims 7 and 9 depend on claim 5. Since claim 5 is patentable, claims 7 and 9 are likewise patentable and the rejection of these claims should be reversed.

V. REJECTION UNDER 35 U.S.C. §103(a) OVER SHUTT ET AL. (U.S. PAT. NO. 5,507,772) IN VIEW OF MATTHEWS ET AL. (U.S. PAT. NO. 6,427,351)

Claims 22-24

A proper rejection under §103(a) has not been established in regard to independent claim 22. Claim 22 calls for each elongate substantially flexible distance reference to have a beveled distal end. The specification of the present application teaches: “To enable more precise measurements, the distance references 166, 168 in the embodiment of FIGS. 20-24 have beveled ends 170, 172. As shown in FIGS. 23-24, the beveled ends 170, 172 are shaped so that the distance references are longest along their inner edges. Thus, the size of a defect, such as a meniscal defect, can be measured by moving the distance references 166, 168 distally or proximally until the longest parts of the beveled ends 170, 172 are aligned with the ends of the defect to be measured.” (page 25, line 19 – page 26, line 2). Thus, the Examiner is incorrect in stating that “Applicant has not disclosed that having beveled ends provides an advantage, is used for a particular purpose, or solves a stated problem.” Moreover, rather than motivating one to bevel the ends of the distance references, Matthews et al. suggests rounded distal ends for the measuring ends of wires (see, e.g. claim 1, col. 6, lines 53-54, claim 24, col. 10, lines 3-4) rather than beveled ends.

Conclusion regarding claims 22-24

Based on the above, the Examiner has not established a proper §103(a) rejection with regard to Appellants’ claim 22. As such, the rejection of independent claim 22, and claims 23-24 depending either directly or indirectly from claim 22, should be reversed.

VI. SUMMARY CONCLUSIONS

Therefore, in view of the arguments presented above, it is submitted that:

- i. the 35 U.S.C. §112, first paragraph rejection of claims 1-4 is erroneous;
- ii. the 35 U.S.C. §102(b) rejection of claims 16-19 based on Shutt et al., U.S. Patent No. 5,507,772 is erroneous;
- iii. the 35 U.S.C. §103(a) rejection of claims 16-19 based on Lucey et al., U.S. Patent No. 5,782,834, in view of Shutt et al., U.S. Patent No. 5,507,772 is erroneous;

- iv. the 35 U.S.C. §103(a) rejection of claims 5-6 and 11 based on Steadman et al., U.S. Patent No. 5,928,252, in view of Troutner et al., U.S. Patent No. 4,091,880 is erroneous; and
- v. the 35 U.S.C. §103(a) rejection of claims 22-24 based on Shutt et al., U.S. Patent No. 5,507,772, in view of Matthews et al., U.S. Patent No. 6,427,351 is erroneous.

The Board is thus urged to reverse these rejections. Such action is respectfully requested.

Respectfully submitted,

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CLAIMS APPENDIX: APPEALED PENDING CLAIMS OF THE PRESENT APPLICATION

1. A surgical instrument having a proximal end and a distal end, the instrument comprising:
 - a handle at the proximal end, the handle including a grip portion;
 - a hollow elongate support member extending distally from the handle and having a distal end at the distal end of the instrument;
 - a slide member having a proximal end and a distal end and a through-slot between the two ends, the through-slot extending in a proximal-distal direction and being located on the proximal side of the hollow elongate support member;
 - a lever pivotally connected to the handle, the lever including a grip portion on one side of the pivotal connection and an integral drive portion on the other side of the pivotal connection, at least part of the drive portion comprising an integral cam received in the slot in the slide member;
 - a surgical implement having a proximal end connected to the distal end of the slide member, an elongate portion extending through the hollow elongate support, and a distal end;
 - a spring to urge the slide member toward the proximal end of the instrument;
 - wherein the slide member and elongate portion of the surgical implement are capable of being moved reciprocally in a linear proximal-distal direction by pivoting the lever; and
 - wherein the surgical instrument is free of any mechanical connection between the lever and the slide member.
2. The surgical instrument of claim 1 wherein the handle has a proximal opening aligned with the slide member, a channel extending distally from the proximal opening, and an entry slot in communication with the channel, wherein the elongate portion of the surgical implement and slide member can be assembled into a subassembly by connecting the elongate portion of the surgical implement to the slide member, and wherein the surgical instrument can be assembled by inserting the subassembly through the proximal opening in the handle, inserting the drive portion of the lever through the entry slot in the handle and into the slot in the slide member, and pushing the elongate portion of the surgical implement through the elongate support member.
3. The surgical instrument of claim 1 further comprising a housing around at least a portion of the slide member, wherein the elongate support member and surgical implement extend outward

from the housing, and wherein the housing, slide member, elongate support member and surgical implement comprise a cartridge removable from the handle and lever.

4. The surgical instrument of claim 3 wherein the housing has a proximal opening aligned with the slide member, a channel extending distally from the proximal opening, and an entry slot in communication with the channel, wherein the elongate portion of the surgical implement and slide member can be assembled into a subassembly by connecting the elongate portion of the surgical implement to the slide member, and wherein the cartridge can be assembled by inserting the subassembly through the proximal opening in the housing, inserting the drive portion of the lever through the entry slot in the housing and into the slot in the slide member, and pushing the elongate portion of the surgical implement through the elongate support member.

5. A modular surgical instrument comprising an actuator module and a discrete tool module, the actuator module comprising:

a handle comprising a grip portion and an integral support portion, the support portion having proximal and distal ends and a support surface between the proximal and distal ends, the handle being substantially open above the support surface; and

a lever pivotally connected to the support portion of the handle, the lever including a trigger portion and a drive portion, the trigger portion being longer than the drive portion, the drive portion extending through an opening in the support surface of the handle; and

the tool module comprising an assembly of a hollow housing, a discrete hollow elongate support member, a discrete surgical instrument and a discrete slide member;

the hollow housing having proximal and distal ends;

the hollow elongate support member being fixed to the distal end of the housing, the hollow elongate support member having a proximal end within the housing and extending outwardly from the housing to a free distal end, the free distal end having an opening;

the hollow housing and hollow elongate support member defining an open passageway between them;

the surgical implement being capable of reciprocal motion in the proximal-distal direction relative to the hollow elongate support member, at least part of the surgical implement extending through the hollow elongate support member and out through the opening at the free distal end of the

elongate support member, the surgical implement having a proximal part extending past the proximal end of the hollow elongate support member into the housing; and

the slide member being operably connected to at least part of the surgical implement and being capable of reciprocal motion in the proximal-distal direction relative to the housing, the slide member having a drive surface within the housing;

wherein the actuator module and tool module are capable of being assembled and disassembled so that at least one of the modules can be reused independent of the other module, and

wherein when the actuator module and tool module are assembled the drive portion of the lever engages the drive surface of the slide member so that the slide member and surgical implement can be moved in the distal direction by squeezing the trigger portion of the lever.

6. The modular surgical instrument of claim 5 wherein the slide member has an elongate slot and the housing of the tool module has an opening aligned with the elongate slot so that the actuator module and tool module can be assembled by inserting the drive portion of the lever through the opening in the housing of the tool module and into the elongate slot in the slide member.

7. The modular surgical instrument of claim 5 wherein the surgical implement comprises a pair of elongate substantially flexible distance references connected at one end to the slide member in the housing and extending out of the free distal end of the elongate support member.

9. The modular surgical instrument of claim 5 wherein the surgical implement comprises a pair of elongate distance references connected at one end to the slide member in the housing and extending out of the free distal end of the elongate support member to free ends, the elongate distance references being made of a shape memory material and having at least one of the following unstressed shapes: substantially straight and parallel; and divergent at the free ends.

11. The modular surgical instrument of claim 5 wherein the surgical implement comprises a cannula, wherein the cannula is received in the elongate support member and connected at one end to the slide member.

12. The modular surgical instrument of claim 5 wherein the instrument comprises a kit including the actuator module and the tool module as separate elements of a kit.

13. The modular surgical instrument of claim 12 wherein the kit includes a plurality of tool modules.
14. The modular surgical instrument of claim 5 wherein the handle is sized and shaped to support the housing of the tool module and to limit relative proximal-distal movement between the housing of the tool module and the handle.
15. The modular surgical instrument of claim 5 wherein at least one of the actuator module and tool module includes a spring for urging the slide member toward the proximal end of the housing.
16. A disposable surgical tool module for use with a separate actuator module, the surgical tool module comprising:
- a housing having proximal and distal ends;
 - a discrete hollow elongate support member at the distal end of the housing, the hollow elongate support member having a proximal end received within the housing, the hollow elongate support member extending outwardly from the housing to a free distal end, the free distal end having an opening;
 - a surgical implement capable of reciprocal motion in the proximal-distal direction, the surgical implement having a proximal end within the housing, at least part of the surgical implement extending through the hollow elongate support member and out through the opening at the free distal end of the elongate support member; and
 - a slide member held within the housing and operably connected to the proximal end of the surgical implement between the proximal end of the housing and the proximal end of the hollow elongate support member, the slide member being capable of reciprocal motion in the proximal and distal directions, the slide member having a slot within the housing;
 - the housing having an opening aligned with the slot of the slide member;
 - the tool module being free from any structure for moving the slide member in the distal direction.

17. The disposable surgical tool module of claim 16 wherein the surgical tool module comprises part of a kit, the kit further including an actuator module including a handle for receiving and supporting the housing of the surgical tool module and a lever pivotally attached to the handle.

18. The disposable surgical tool module of claim 16 wherein the surgical implement comprises at least one of the following:

- a pair of elongate substantially flexible distance references connected at one end to the slide member in the housing and extending out of the free distal end of the elongate support member;

- an elongate rod and a tissue manipulator, wherein the elongate rod is received in the elongate support member and connected at one end to the slide member and at the other end to the tissue manipulator; and

- a cannula connected at one end to the slide member.

19. The disposable surgical tool module of claim 16 further comprising a spring in the housing for urging the slide member toward the proximal end of the housing.

21. The disposable surgical tool module of claim 16 wherein the surgical implement comprises a pair of elongate distance references connected at one end to the slide member in the housing and extending out of the free distal end of the elongate support member to free ends, the elongate distance references being made of a shape memory material and having at least one of the following unstressed shapes: substantially straight and parallel; and divergent at the free ends.

22. A surgical instrument having proximal and distal ends comprising:

- a handle at the proximal end, the handle including a grip portion;

- a hollow elongate support member extending outward from the handle in a distal direction;

- a surgical implement extending through the elongate support member and capable of reciprocating in the proximal-distal direction in the elongate support member;

- a lever pivotally connected to the handle, the lever including a trigger portion and a drive portion, the trigger portion being longer than the drive portion, the lever extending through an opening in the handle; and

- a slide member having a drive surface engaging the drive portion of the lever, the slide member being capable of reciprocal motion in the proximal-distal direction;

wherein the surgical implement comprises a pair of elongate substantially flexible distance references connected at one end to the slide member and extending out of the distal end of the elongate support member;

wherein the elongate support member has a substantially cylindrical portion and a pair of discrete elongate tubes extending from the substantially cylindrical portion to beveled distal ends, the discrete elongate tubes having substantially parallel portions and curved divergent portions; and

wherein one of the elongate substantially flexible distance references extends through one of the discrete elongate tubes and the other elongate substantially flexible distance reference extends through the other of the discrete elongate tubes, and wherein each elongate substantially flexible distance references has a beveled distal end.

23. The surgical instrument of claim 22 wherein the curved portion of each discrete elongate tube has a radius of curvature greater than 12.7 cms.

24. The surgical instrument of claim 22 further comprising a wedge between the curved portions of the discrete elongate tubes, the wedge including distance indicia.

EVIDENCE APPENDIX

Nothing is included with this appendix.

RELATED PROCEEDINGS APPENDIX

Nothing is included with this appendix.